REMARKS

Claims 49 to 86 and 133 to 145 remain pending in the application and stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,618,845 ("the '845 patent"). While Applicants respectfully disagree with this rejection, as discussed in the response submitted March 23, 2006, independent claims 49 and 134 have been amended herein in an effort to advance prosecution of the application. Applicants respectfully submit that the instant amendments place the application in condition for allowance, and raise no new issues that would require an additional search. Accordingly Applicants respectfully request entry of this amendment after final.

Claims 49 and 134 have been amended to clarify that the recited dosage units comprise modafinil particles from at least one small particle discrete lot and modafinil particles from at least one large particle discrete lot. The amendment is supported throughout the specification, with definitions of the terms "small particle discrete lot" and "large particle discrete lot" provided at page 8, lines 7 to 20. No new matter is added.

As discussed in the specification, the inventors have found that by customizing and controlling the particle size distribution of a blend of small and large particles of modafinil, the dissolution and absorption properties of a dosage form of modafinil can be optimized. One method of achieving this customization and control comes from preparing discrete lots of modafinil particles, and combining particles from these discrete lots into a dosage form having the desired dissolution and absorption properties.

The '845 patent fails to teach or suggest dosage units that contain particles obtained from small particle discrete lots and large particle discrete lots as recited in the amended claims, and indeed teaches away from such units. For example, the '845 patent states at col. 9, lines 40 to 43 that "a non-homogeneous mixture of modafinil particle sizes may not provide consistent potency nor avoid undesired fluctuations in plasma modafinil concentrations; such fluctuations can lead to undesired and unexpected results." This teaching is reflected in the claims of the '845 patent, which recite a pharmaceutical composition that contains a "substantially homogeneous mixture of modafinil particles." Thus, the '845 patent *teaches away* from preparing a dosage form that comprises combinations of particles from discrete lots of varying sizes, as is the subject of the instant

application. Accordingly, Applicants request that the rejection under Section 103 over the '845 patent be reconsidered and withdrawn.

Applicants respectfully submit that the instant application is now in conditions for allowance. A notice of allowance for all of pending claims 49 to 86 and 133 to 145 is therefore requested respectfully.

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